

MANDAREE MEDICAL COMPANY

P.O. Box 1791

1720 Burnt Boat Drive

Bismarck, ND 58502

(701) 223-9206

FAX (701) 224-0017

2928 '00 JUN 14 19:57

June 12, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: Docket Nos. 92N-0297 and 88N-0258

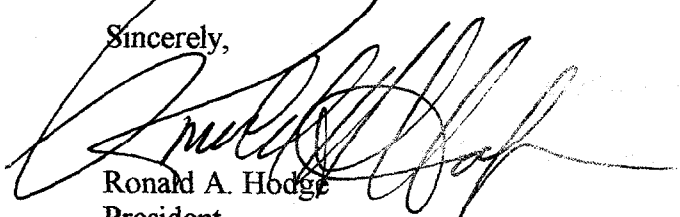
Dear Sir:

We purchase wholesale pharmaceuticals from various wholesale distributors and manufacturers. It is our corporate understanding that the Food and Drug Administration is requiring a more extensive prescription drug sales history and information pertinent to the 1988 FDA PDMA. As a result, this corporation may be put out of business by these new regulations. This corporation has sent out 80 letters to pharmaceutical manufacturers, all of which were mailed certified, return receipt. We have only received three (3) letters in return. We were informed by another major manufacturer that they were not interested in any new business and did not wish to have us as wholesale distributors of their products.

As we are a small Native American company, this could place us in jeopardy of going out of business. We feel that the pharmaceutical manufacturers have not only been discriminatory, but not receptive to any new authorized distributors. Our request to manufacturers pursuant to the guidance provided by the proposed regulations has been thoroughly ignored. We have attempted to become a small wholesale distributor of Pfizer for the past three (3) years and have been denied all access to that company.

This corporation supports a return to the guidance issued by the FDA in August, 1988 in respect to the Prescription Drug Marketing Act and authorized distributors.

Sincerely,


Ronald A. Hodge
President

mhw

88N-0258

C90